

Proposed Tuberculosis and Brucellosis Regulatory Framework



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Vision for TB and Brucellosis Regulations

- Develop a draft regulatory framework
- Single rule for both TB and brucellosis programs
 - Ensures consistency
 - Increases flexibility
 - Reduces administrative burden
- Performance standards to be included in the CFR; details in a Program Standards document



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Scope of TB and Brucellosis Regulations

- Program (host) species – Cattle, bison, and captive cervids
- Agent species – *Mycobacterium bovis* and *Brucella abortus*

Regulatory Element 1— Program (State) Requirements

Regulatory Components

1. State status – Three-tier system
2. General program requirements
3. Reporting requirements
4. Compliance and accountability



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Program (State) Requirements (Continued)



States/Tribes to develop, submit, and implement animal health plans

State X Plan

- Legal authority and resources
- Surveillance
- Case management and response procedures and reporting
- High-risk subpopulations
- Potential wildlife reservoirs
- Risk mitigation activities
- Proposed approach for zoning

VS approves and State implements



State X classified as
“Consistent”

VS does not approve or State fails to implement



State X classified as
“Provisionally consistent”

State X classified as
“Inconsistent”

Specific regulatory consequences are imposed.



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Program (State) Requirements (Continued)

General Program Requirements

- Develop infrastructure, laws, and regulations to implement and enforce TB and brucellosis programs
- Implement a reportable disease process
- Develop and implement a comprehensive animal health plan that meets APHIS performance standards jointly approved by the State or Tribe and the Administrator (VS will make publically available)



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Program (State) Requirements (Continued)



Reporting Requirements

- State and/or Tribes must report, as transparency is critical for success of the program
 - Implementation of animal health plan
 - Epidemiological investigations
 - Caudal fold response rates
- The animal health plan should include a description of how States and Tribes will coordinate their reporting



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Program (State) Requirements (Continued)

Compliance and Accountability

- Accountability for States and Tribes must be built into status system
- Compliant States and Tribes will not be subject to Federal interstate movement restrictions or testing requirements
- Noncompliance options include reduction in status or other consequences (increased testing requirements, loss of funding, increased surveillance requirements)



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Regulatory Element 2—Zoning

Regulatory Components

- Short-term containment
 - Address finding of affected herd(s) or presence of disease in wildlife without livestock involvement
- Long-term containment (>1 yr)



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Zoning—Short-term Containment

- Herd(s) are quarantined and standard epidemiological investigation conducted (following protocol outlined in program standards)
- State or Tribe implements action (case management and response) outlined in animal health plan
- Goal of the containment action is eradication
- Action ends with release of quarantine



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Zoning—Long-term Containment (>1 yr)

- Developed by State/Tribe if eradication cannot be achieved within a year
 - Assessment of the plan may involve consultation with the advisory board
 - Plan may be approved provisionally
 - If necessary, VS conducts risk assessment in collaboration with the State/Tribe
 - VS approves or disapproves containment plan
 - Action ends with eradication of the disease



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Example: Brucellosis Management Areas and TB Federal Order

- State with a known brucellosis-affected wildlife population or with other circumstances must develop and implement brucellosis management plan
- Plan must define and explain the basis for the geographic area in which a disease risk exists
- No automatic downgrade for entire State under TB Federal Order



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Regulatory Element 3—Surveillance

Regulatory Components

- National surveillance: Slaughter and other surveillance
- Targeted surveillance: At-risk populations as indicated in the animal health plan
- Other surveillance to support the State/Tribe plan and national plans
- Surveillance will require animal ID; must be consistent with traceability rule



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Regulatory Element 4— Affected Herd Management and Epidemiological Investigations (AHMEI)

Regulatory Components

- Provides definitions of terms
- Identifies who determines when a herd (or other group of animals) is affected and how affected herds are managed, including development of a herd plan
- Provides for the development of investigation and reporting requirements and timeframes for epidemiological investigations



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Regulatory Element 4—AHMEI

Regulatory Components (Continued)

- Allows consequences if epidemiological investigations aren't conducted properly or within specified timeframes
- Provides conditions for variances from program requirements
- Allows facilities to receive high-risk or restricted movement animals



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Regulatory Element 5—Indemnity

Background

- Flat or declining Federal budgets
 - TB (\$16.8 million to \$15.6 million)
 - \$1 million in indemnity
 - Brucellosis (\$9.7 million to \$9.2 million)
 - \$ 500,000 in indemnity
- Past reliance on CCC funding
 - TB indemnity average of \$5 million/year
- Average of 60 days to depopulate



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Regulatory Element 5—Indemnity (Continued)

Regulatory Components

- Defines terms specific to indemnity
- Indicates that indemnity payments are contingent upon the availability of Federal funds
- Describes the approach for indemnity
- Process will be described in program standards, not the CFR, so it can be changed more efficiently



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Regulatory Element 5—Indemnity

Regulatory Components (Continued)

- Describes how indemnity values for individual animals will be determined
 - Appraisal calculator (based on age, weight, milk production, and regional values)
 - Defined transparent process for updating calculator
 - Indemnity paid (100% fair market value) based on calculator value
 - No appeal process



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Beef Calculator (An Example)

- Developed by Livestock Marketing Information Center (Dr. Darrell Peel)
- Reviewed by Dr. Shannon Neibergs, Washington State University
- Covers bred heifers, bred cows, cow-calf pairs, and herd bulls
- Base price based on slaughter cow value with consideration given to cow's age, cow/bull weight, calf age, and quality
- Considers pricing in five different regions
- Salvage value to be subtracted from indemnity payment



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Regulatory Element 5—Indemnity

Regulatory Components (Continued)

- Describes eligible indemnity expenses
 - Full payment for animals destroyed, transported, and disposed of
 - No payment for cleaning
 - Possible payment for disinfection on a case-by-case basis



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Regulatory Element 6— Interstate Movement Controls

Regulatory Components

- Allow interstate/Tribal/area movement controls for animals that pose a risk of disease spread
- Provide the authority to define what types and classifications of animals and herds might be subjected to movement controls (example: breeder animals out of a high-risk area)



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Regulatory Element 6— Interstate Movement Controls

Regulatory Components (Continued)

- Consequences may be applied for lack of implementation or maintenance of risk-mitigation measures, or noncompliance with restrictions
- Active mitigation activities may preclude or diminish the need for movement controls (e.g., terminal feedlots, use of approved disease management plans)



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Regulatory Element 6— Interstate Movement Controls

Regulatory Components (Continued)

The Administrator can, in specific cases and in consultation with or advisement by the advisory board, consider variances from the movement restrictions when spread of disease has been mitigated



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Regulatory Element 7— Importation Requirements

Stages

- Pre-Import
- Import
- Post-Import



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Regulatory Element 7— Pre-Import Requirements

Regulatory Components

- Risk of disease in the region of origin of imports is determined
 - 9 CFR part 92 – 11 factors for regionalization
- Requirements should ensure that animals offered for import to the U.S. are disease free



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Regulatory Element 7— Pre-Import Requirements (Continued)

- Import requirements may be increased after a threshold (prevalence, number of slaughter cases, caudal fold response rates) has been reached
- Import restrictions may be eased if zone shows improvement
- Improvements may be verified by onsite program review



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Regulatory Element 7— Importation Requirements—Import

Regulatory Components

- First point of concentration (mingling) after entry must be identified and documented
- Records must be maintained to facilitate animal tracing
 - If animals will be moved interstate from first point of concentration, State of destination must be notified before movement takes place



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Regulatory Element 7— Post-Import Requirements

Regulatory Components

- General Requirements
 - Continuity of official identification (country of origin)
 - ICVI/brand inspection required for interstate movement
 - Consistent with traceability regulations
- Post-entry restrictions and long-term testing requirements
 - Imported steers and spayed heifers must be maintained separately from domestic breeding cattle
 - Periodic testing of event/rodeo cattle



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Program Element 8— Approval Procedures Related to Official Tests and Laboratories

Regulatory Components

- Defines pertinent terms
- Process of initial approval and recertification/continued approval of official diagnostic tests, official testing laboratories, and official testers
- Changes to be accomplished through a published notice describing proposed change and soliciting public comment



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Program Element 8— Approval Procedures Related to Official Tests and Laboratories

Regulatory Components (Continued)

- Provides a mechanism to withdraw or suspend approval
- Provides quality assurance and quality control for testing laboratories and proficiency testing of authorized personnel



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Questions?

